In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-0545V

UNPUBLISHED

EDDIE DEAN BENENHALEY, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: November 28, 2022 Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Guillain-Barré Syndrome (GBS)

Vasiliki D. Koutsogiannis, Law Office of James Snell, Jr., Lexington, SC, for Petitioner.

Kimberly Shubert Davey, U.S. Department of Justice, Washington, DC, for respondent.

DECISION DISMISSING CASE[1]

On May 1, 2020, Eddie Dean Benenhaley filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that he suffered from Guillain-Barré syndrome ("GBS") as a result of an influenza ("flu") vaccine he received on September 3, 2018. Petition at 1. This case was assigned to the Special Processing Unit of the Office of Special Masters.

On January 12, 2022, Petitioner was ordered to show cause why this case should not be dismissed. ECF No. 35. Petitioner filed a response on March 15, 2022. ECF No. 36 ("Opp."). For the reasons discussed below, this claim is hereby **DISMISSED**.

[1] Although I have not formally designated this Decision for publication, I am required to post it on the United States Court of Federal Claims' website because it contains a reasoned explanation for the action in this case, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

The Petition specifically alleges a "non-Table" or causation-in-fact claim, even though a Table claim exists for GBS occurring after receipt of the flu vaccine. Petition at ¶23. An initial status conference was held on June 29, 2021, during which two significant issues were discussed. First, Respondent noted that Petitioner had not yet filed a record of the vaccination (*see* ECF No. 23), although that omission has since been rectified. ECF No. 33. Second, Respondent noted that the record seemed to establish onset of Petitioner's GBS *14 weeks* after his vaccination – not only too long for a Table claim, but far in excess of what the Program has recognized as medically reasonable for non-Table flu vaccine-GBS claims - and indicated that he would defend the case on that ground. ECF No. 23.

On August 30, 2021, Respondent filed his Rule 4(c) Report specifying in greater detail the basis for his objection. Rule 4(c) Report at 6. Specifically, Respondent argued that Petitioner "has not offered any evidence to show a logical sequence of cause and effect showing that the vaccination caused his GBS, or that the fourteen-week period between vaccination and the onset of his GBS is a timeframe within which vaccine causation could be ascribed." *Id.* at 7. In light of this argument, I Ordered Petitioner in January 2022 to show cause why this claim should not be dismissed.[3] ECF No. 35. Petitioner filed his brief ("Br.") in opposition (ECF No. 36), Respondent filed a memorandum of his own ("Resp Br.") on April 28, 2022 (ECF No. 37), and Petitioner filed a reply ("Repl.") on May 13, 2022. ECF No. 39. The matter is ripe for resolution.

II. Factual Background

Petitioner was 57 years old when he received the flu vaccine at a Walgreens in Sumter, South Carolina, on September 3, 2018. Ex. 10 at 2-3; Petition at ¶1. Petitioner's medical history prior to his vaccination included shoulder surgery, prostate cancer, diverticulitis, coronary artery disease, and renal insufficiency. Ex. 9 at 3. At the time of his vaccination, Petitioner was employed part-time, was an umpire on his local baseball team, and cared for his disabled wife. Affidavit at ¶3, 20.

Petitioner has stated that in November 2018, between his influenza vaccination in September and the onset of his symptoms in December, he received a shingles vaccination. Affidavit at ¶7; Petition at ¶3.[4] There are otherwise no medical records in the

[3] I also cautioned Petitioner's counsel that if the response to the show cause order relied primarily on witness testimony aimed at establishing that Petitioner's symptoms began sooner than the medical records establish, reasonable basis issues would be raised that could imperil some of the fees to which counsel would otherwise be entitled. ECF No. 35 at 2.

[4] Petitioner did not file the record of his shingles vaccination.

intervening timeframe establishing any adverse effects of the early September vaccination.

On December 21, 2018 (109 days after the relevant vaccination), Petitioner presented to the emergency room with numbness and weakness in his lower extremities. Ex. 5 at 357. Petitioner reported that his symptoms began the previous day, and progressively worsened to include his upper extremities.[5] *Id.* He also mentioned that he had an upper respiratory infection two weeks earlier, from which he continued to have a cough and shortness of breath. *Id.*

Petitioner was admitted to the hospital, diagnosed with GBS, and began IVIG treatment. Ex. 5 at 358-59. While hospitalized, Petitioner experienced respiratory distress and spent two days in the intensive care unit. *Id.* at 369-73. The treating neurologist noted on December 27, 2018, that Petitioner had a shingles vaccine two weeks prior. *Id.* at 374. On December 28, 2018, Petitioner was discharged to an inpatient rehabilitation facility. *Id.* at 361. He continued to have lower extremity weakness and was unable to walk on his own. *Id.* at 361. Petitioner remained at the facility through January 17, 2019, when he was discharged home. Ex. 6 at 13-34.

On January 24, 2019, Petitioner presented to his primary care physician ("PCP"). Ex. 8 at 31-32. The doctor noted that Petitioner had been hospitalized after "acute onset of bilateral lower extremity weakness and numbness," after an "upper respiratory infection two weeks prior." *Id*. at 32. Petitioner's legs were swollen at the visit and a venous study revealed deep vein thrombosis in both legs. *Id.*

On January 28, 2019, Petitioner presented to the emergency room complaining of shortness of breath and chest pain. Ex. 7 at 4. He was hospitalized for treatment of bilateral pulmonary embolism through February 5, 2019, when he was transferred to an inpatient rehab facility for physical and occupational therapy. *Id*. at 4-5. Petitioner was discharged from rehab to home on March 1, 2019. Affidavit at ¶9.[6]

From April 12, 2019 through September 3, 2019, Petitioner received outpatient physical therapy for his GBS related symptoms, including his ability to walk and care for himself. Ex. 4. During the initial evaluation, the physical therapist noted that Petitioner's "symptoms began after getting shingles shot." *Id.* at 5. By the time of his discharge, Petitioner was independent with activities of daily living. *Id.* at 203.

[5] Petitioner stated in both his Petition and Affidavit that his symptoms began the day of his hospitalization, rather than the day prior. Petition at ¶4; Affidavit, dated April 7, 2020, at ¶1, 8.

[6] Petitioner did not file the records of his second stay in inpatient rehab.

On December 3, 2019, Petitioner returned to his PCP for a follow-up appointment. Ex. 8 at 17. The doctor noted that Petitioner made a "dramatic recovery" and that "his only symptom at present is some tingling in the posterior calves." *Id.* On January 7, 2020, Petitioner returned for a sick visit and reported no ongoing neurological symptoms. *Id.* at 15.

In addition to the medical records, Petitioner submitted an affidavit signed on April 7, 2020. Petitioner states that he has "regained partial mobility" and "was able to walk short distances." Affidavit at ¶13. He notes that he has not fully recovered and still experiences fatigue, weakness, and numbness and tingling in his feet. *Id.* at ¶13-14.

III. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his/her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). However, although later oral testimony that conflicts with medical records is less reliable, it is appropriate for a special master to credit a petitioner's lay testimony where is does not conflict with contemporaneous records. *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1382-84 (Fed. Cir. 2021).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[7] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he received. Section 11(c)(1)(C). For both Table and Non–Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter., Inc. v. United States*, 6 Cl. Ct. 476, 486 (1984) (explaining that mere conjecture or speculation is insufficient under a preponderance standard).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non–Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." Each *Althen* prong requires a different showing and is discussed in turn along with the parties' arguments and my findings.

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence

[7] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11–355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, GBS is compensable if it manifests within 3-42 days (not less than three days and not more than 42 days) of the administration of an influenza vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). (Further criteria for establishing a GBS Table Injury case be found under the accompanying qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(15)). Any onset outside that timeframe prevents the matter from succeeding as a Table claim, although it can often still be maintained as a non-Table, causation-in-fact claim.

Cases alleging a Table GBS/flu vaccine claim are often dismissed for failure to establish the proper onset. *See,* e.g., *Randolph v. Sec'y of Health & Human Servs.*, No. 18-1231V, 2020 WL 542735, at *8 (Fed. Cl. Spec. Mstr. Jan. 2, 2020) (finding GBS onset at the earliest occurred 76 days post-vaccination, "well outside the 3-42-day window set by the Table for a flu-GBS claim"). Further, in adjudicating non-Table versions of such a claim, special masters have frequently noted that six to eight weeks is the longest medically-acceptable timeframe recognized in the Vaccine Program for onset of post-flu vaccine GBS. *See, e.g.*, *Chinea v. Sec'y of Health & Human Servs.*, No. 15-095V, 2019 WL 1873322, at *33 (Fed. Cl. Mar. 15, 2019), *mot. for review den'd*, 144 Fed. Cl. 378 (2019) (onset of the petitioner's GBS occurred eleven to twelve weeks after her vaccination, well beyond the six- to eight-week medically appropriate timeframe for the occurrence of vaccine-induced GBS); *Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (finding eight weeks

(or 56 days) is the longest reasonable timeframe for a flu vaccine/GBS injury).

IV. Finding of Fact

Petitioner alleges that he suffered from GBS that was caused-in-fact by a flu vaccine administered on September 3, 2018. Petition at 2. As the Petition itself alleges that the onset of symptoms occurred on December 21, 2018, Petitioner does not attempt to argue that his onset falls within the Table's window between 3 and 42 days after vaccination. *Id*. at ¶4. In fact he could not – his affidavit and contemporaneous medical records preponderantly establish that the initial symptoms occurred, at the earliest, on December 20, 2018, as Petitioner reported at during his first visit to the emergency room, or on December 21, 2018, as Petitioner reported in his Petition and Affidavit. Ex. 5 at 357; Petition at ¶4; Affidavit at ¶8. This puts the onset of Petitioner's GBS at *108 or 109 days* (or approximately 15 weeks) after his influenza vaccination.

There is no dispute that Petitioner's records consistently suggest an onset of GBS symptoms on December 20 or 21, 2018. *See* Br. at 2. This fact not only puts Petitioner's claim outside the 42-day limit for a viable Table flu-GBS claim, but at almost double the length of the *longest time* accepted for a similar non-Table claim. *See, e.g.*, *Chinea*, 2019 WL 1873322, at *33; *Barone,* 2014 WL 6834557, at *13. Accordingly, there is a glaring facial deficiency with Petitioner's claim – since it appears at the outset that he cannot preponderantly establish the third *Althen* prong.

Petitioner makes no argument that the onset of his symptoms was closer to the time of vaccine administration, or within the six to eight-week timeframe that prior Program cases have embraced. Instead, he argues he did not "suffer from neurological issues prior to the vaccine's administration" and was in "good health" – concluding that "therefore, a nexus between the vaccine in question (quadrivalent flu vaccine) and Petitioner's medical issues which arose after the vaccine was administered exists." Br. at 4.

Of course, the mere fact that Petitioner was in good health prior to the flu vaccine and developed GBS 15 weeks after the vaccination does not provide preponderant evidence that the flu vaccine *caused* Petitioner's GBS. This is precisely the kind of *post hoc ergo propter hoc* reasoning that the Program rejects. *See Galindo v. Sec'y of Health & Human Servs.,* No. 16-203V, 2019 WL 2419552, at *20 (Fed. Cl. Spec. Mstr. May 14, 2019). And there are sound reasons for the Program not simply assuming that any post-vaccination injury is attributable to it. Petitioner's GBS could certainly be a coincidence, or have an alternative cause, such as his shingles vaccine or his upper respiratory

infection, both of which occurred in closer proximity to his diagnosis than did his flu vaccination.[8]

Petitioner further argues that the conclusion that he contracted GBS "after a delayed onset from the quadrivalent vaccine . . . cannot be excluded with confidence" based on his medical records. Br. at 2. However, Petitioner misstates his burden in this case. It is not sufficient that there is a *possibility* that his flu vaccine caused his GBS; Petitioner must provide evidence that is it more likely than not that the flu vaccine directly caused his GBS. And the lengthy timeframe from vaccination to onset greatly reduces the likelihood that the two events are *at all* related.

In order to overcome the Program's consistent reaction to overly-long post-vaccination GBS onset, Petitioner has attempted to offer medical literature to support his argument that "it cannot be argued that onset of GBS following vaccination does not occur or cannot occur past the time periods set forth in the table (or past the longest accepted period before this Court)." Repl. at 2. Petitioner further states that "the question of prolonged onset is hardly settled," and that "it cannot be concluded that there is no basis in the scientific literature for accepting an onset period of GBS following a seasonal influenza vaccine well past the 42-day window, including and especially after 109 days. . . ." *Id.* at 3.

A close reading of Petitioner's medical literature, however, reveals that it does not support his argument, other than acknowledging that there are occasional instances in which individuals incur GBS long after receipt of the flu vaccine. *See* M. Petras, *et al., Is an Increased Risk of Developing Guillain-Barré Syndrome Associated with Seasonal Influenza Vaccination? A Systematic Review and Meta-Analysis*, Vaccines (Basel) 2020 March 27; 8(2):150 ("Petras Article"). First, the Petras Article is limited to the inactivated trivalent influenza vaccine, not the quadrivalent vaccine that Petitioner received. Petras Article at 2. Second, the article focused on determining "a risk estimate of influenza vaccine-associated GBS" and not on any determination of the length of time between vaccination and symptom onset that is medically reasonable. *Id.* The article examined a set of studies, two of which included onset within 180 days, and two of which included onset within 365 days, along with several others with shorter onset periods. *Id.* at 4. Ultimately, the Petras Article's authors concluded that "even if some studies documented, in time windows of less than or equal to 42 or 49 days, a vaccine-associated increase in

[8] Petitioner did not address the November 2018 shingles vaccine or the upper respiratory infection, other than to express that it is his view that the GBS caused the upper respiratory infection, rather than the upper respiratory infection causing the GBS. Repl. at 3. And as already noted, he has not established receipt of the shingles vaccine (which is not a covered vaccine in any event). *Scanlon v. Sec'y of Health & Human Servs.*, 114 Fed. Cl. 135, 143 (2013).

GBS, the pooled risk estimate within 42 and 43-365 days de facto did not demonstrate this marginal association." *Id.* at 8. This contradicts Petitioner's argument.[9]

In addition, there are other reasons to find that this claim is unlikely to be capable of being preponderantly supported. For example, none of Petitioner's medical providers associated his GBS with his flu vaccination. In fact, his providers mentioned his shingles vaccine, purportedly received sometime in November 2018, and his upper respiratory infection two weeks prior to the onset of symptoms as possible causes. *See*, *e.g.* Ex.5 at 357 (Petitioner reported having an upper respiratory infection, with residual symptoms, two weeks prior to his emergency room visit on December 21, 2018); Ex. 5 at 374 (hospital neurologist noted on December 27, 2018 that Petitioner had a shingles vaccine two weeks prior); Ex. 8 at 32 (Petitioner's PCP noted on January 24, 2019 that Petitioner's symptoms began after an upper respiratory infection two weeks prior); Ex. 4 at 5 (physical therapist noted that Petitioner's symptoms began after getting a shingles shot).

At bottom, it is reasonable for special masters to reject claims that are not likely to succeed, even if there is a miniscule possibility of success. The concept that a too-long onset reduces the probability of vaccine causation is not the product of an arbitrary lark by special masters past and present; it is instead a wholly-reasonable interpretation of the third *Althen* prong – which in turn inherently recognizes that as time passes from a vaccination event, the likelihood the vaccine was responsible for it (as opposed to intervening events) diminishes. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1358-59 (Fed. Cir. 2006). The medical science that strongly supports post-flu vaccine causation in the Table period, or somewhat less so a week or two beyond, falls out entirely when onset is alleged to have been as long as in this case.

CONCLUSION

Despite ample opportunity, Petitioner has failed to offer a persuasive, preponderantly-supported argument or explanation in response to my Order to Show Cause, as to why his claim should not be dismissed for failure to establish that onset of his GBS occurred in a medically acceptable timeframe. Accordingly, I must **DISMISS** his claim in its entirety. **The Clerk shall enter judgment accordingly.**[10]

[9] The Petras Article also reported that there was a "strong association of GBS with influenza, influenza like illness, or upper respiratory infection," rather than with vaccination, thus supporting the argument that Petitioner's GBS could likely have been caused by his closer-in-time illness. *Id.* at 8-9.

[10] If Petitioner wishes to bring a civil action, he must file a notice of election rejecting the judgment pursuant to § 21(a) "not later than 90 days after the date of the court's final judgment."

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master